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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/914,684 | 01/10/2002 | Eric M. Nelson | P-LX 4948 | 2349 |

23601 7590 10/20/2003
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EXAMINER

DAVIS, DEBORAH A

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/20/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/914,684

Applicant(s)

NELSON ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7-21-03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 is/are allowed.
- 6) ☒ Claim(s) 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action mailed April 23, 2003 (Paper #7) is acknowledged. Currently, claims 1-7 are pending and under consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al (USP#6,024,919).

Nelson et al anticipates the instant claims by teaching a method and apparatus for controlling the absorption of a liquid sample. Nelson et al provides a method and apparatus of manufacture for receiving a liquid sample, such as blood and other body

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fluids (column 2, lines 47-50) where a first portion of the polymer layer overlies a solid surface and a second portion of the polymer layer overlies a window (see abstract).

Sonic treatment of the polymer layer will selectively reduce the void volume of a sintered polymer layer such as a porous high-density polyethylene (see abstract). The apparatus contains a reaction layer comprising reagents that can react with specific analytes in a liquid sample (column 2, lines 61-62). The apparatus has an air gap (column 6, lines 45-49) comprising a space or hole between two separate solids (see Figure 2, 4b) and a reflectance monitor (translucent window) for view color reactions and changes in the reaction layer (column 9, lines 58-65). The apparatus also comprise of at least one sidewall and wherein the layers, walls and window define an air gap (see abstract and Figure 2). Nelson et al teaches an absorbent polymer of BIODYNE A 0.65 μm (col. 12, lines 12-13) that is permeable to gases and liquid (col. 3, lines 36-40). With respect to the limitation "such that the air pressure of the air gap is increased, thereby controlling liquid sample absorption by the absorbent layer" it is the Examiner's position that since the Nelson et al reference teaches the same type of absorbent layers taught in applicant's specification (BIODYNE), it is inherent that the air gap will increase when liquid is applied.

Response to Arguments

4. Applicant's arguments filed July 21, 2003 have been fully considered but they are not persuasive. Applicants' argument that the Nelson et al reference does not teach

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independent claim 4 because it has been amended to recite an "air gap that serves to control liquid sample absorption by an absorbent layer upon application of the liquid sample to that absorbent layer", in addition the air gap is a chamber. This argument is not found persuasive because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the Nelson et al anticipates all of the structural limitations, including amended limitations of independent claims 4-7 that comprise of an air gap (see column 6, 45-49 and Figure 2, 4b). Wherein the air gap is a "chamber", it is the Examiners position that since the Nelson et al reference teaches an air gap, it is inherent that the air gap is a chamber.

This is not intended use, rather it is rather an inherent limitation.

5. Applicants' amended claim 4, recites the limitation "wherein the absorbent layer, at least one sidewall, translucent window and air gap are adapted such that application of a liquid sample to the absorbent layer increases the air pressure of the air gap, thereby controlling liquid sample absorption by the absorbent layer" have been fully considered and are found persuasive. Therefore, the Blatt et al reference of claims 4-7 has been withdrawn.

6. Applicants' claim 1 is amended to recite the application of a liquid sample to an absorbent layer on the opposite of the air gap such that the air pressure of the air gap is increased, thereby controlling liquid sample absorption, have been fully considered and are found persuasive. Therefore, the Burd et al reference of Claims 1-3 has been withdrawn.

Conclusion

7. **For reasons aforementioned above, no claims are allowed.**

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

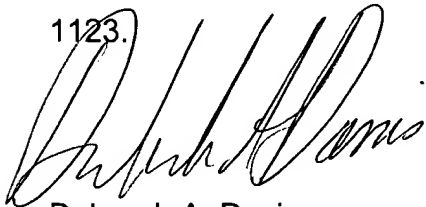
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123.

A handwritten signature in black ink, appearing to read "Deborah A. Davis". The signature is fluid and cursive, with the first name "Deborah" being more prominent than the last name "Davis".

Deborah A. Davis
CM1, 7D16
October 3, 2003